

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

**SANOFI-AVENTIS, SANOFI-AVENTIS
U.S. LLC,**

Plaintiff,

v.

BARR LABORATORIES, INC., et al.

Defendants.

**Civil Action No. 07-1605 (WJM)
(consolidated)**

OPINION

This matter comes before the Court by way of Defendants’ request for leave to submit a reply expert report limited to the issue of secondary considerations of non-obviousness raised by Plaintiff in its rebuttal expert report on invalidity. The Court has considered the parties submissions on the matter, namely Defendants’ letter dated December 23, 2008 and Plaintiff’s letter dated January 14, 2009.¹ No oral argument was heard. Fed. R. Civ. P. 78. For the reasons that follow, Defendants’ request is **denied without prejudice**.

BACKGROUND

A. The ‘531 Patent – Ambien CR®

Sanofi-Aventis, Sanofi-Aventis U.S., LLC (“Sanofi-Aventis” or “Plaintiff”) is the owner of United States Patent No. 6,514,531 (“the ‘531 patent”). The ‘531 patent discloses a pharmaceutical controlled-release dosage form adapted to release zolpidem or a salt thereof over a predetermined time period. Ambien CR® is an embodiment of the ‘531 patent. Ambien CR® was approved by the Food and Drug Administration (“FDA”) on September 2, 2005 for the treatment of insomnia.

¹ The Court notes that neither letter was filed on the public docket, as both contain confidential information.

B. Defendants Seek FDA Approval for Generic Version of Ambien CR®

Defendants, Barr Laboratories, Inc., Mutual Pharmaceutical Co., and Sandoz, Inc. (“Defendants”) each respectively filed an Abbreviated New Drug Application (“ANDA”) pursuant to the Hatch-Waxman Act² seeking FDA approval to sell a generic version of the zolpidem extended-release tablets prior to the expiration of the ‘531 patent. Each ANDA contains a paragraph IV certification. By filing a paragraph IV certification, Defendants have each taken the position that its generic drug does not infringe the ‘531 patent or, in the alternative, that the ‘531 patent is otherwise invalid. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

C. Sanofi-Aventis Sues Defendants for Infringement of the ‘531 Patent

Sanofi-Aventis responded by filing complaints against each Defendant.³ This invoked an automatic stay under the Hatch-Waxman Act which prohibits the FDA from approving the generic until the earlier of: (a) the date on which the ‘531 patent expires, (b) the date on which the Court enters judgment in the infringement lawsuit, or (c) thirty months from the date on which Plaintiff first received notice of Defendants’ respective ANDA paragraph IV filings. See 21 U.S.C. § 355(j)(5)(B)(iii); Allergan, 324 F.3d at 1327.⁴

² For a thorough discussion of the Hatch-Waxman Act, see Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1325-27 (Fed. Cir. 2003).

³ In particular, Plaintiff filed complaints against Watson Pharmaceuticals, Inc. (Civil Action No. 07-443), Mutual Pharmaceutical Co., Inc. (Civil Action No. 07-2250), and Sandoz Inc. (Civil Action No. 08-1190). The complaint against Watson Pharmaceuticals, Inc. was dismissed without prejudice on July 30, 2008. The remaining actions were consolidated for all purposes under Civil Action No. 07-1605.

⁴ See generally Shashank Upadhye, Generic Pharmaceutical Patent and FDA § 2:33 (2008) (“Because the ANDA specifies the ultimate product to be sold, the application forms a quasi document-based litigation.”).

D. Expert Discovery

Expert discovery is scheduled to remain open through August 17, 2009. The Court has directed that all expert reports for the issues on which a party bears the burden of proof are due on April 15, 2009 and that all rebuttal expert reports are due on June 17, 2009. See CM/ECF Docket Entry No. 32. By way of letter to the Court dated December 23, 2008, Defendants request leave to submit a reply expert report on secondary considerations of non-obviousness. The Court now considers Defendants' request.

LEGAL STANDARD

Federal Rule of Civil Procedure 26(a)(2) ("Disclosure of Expert Testimony") provides that "a party must disclose to the other parties the identity of any witness it may use at trial." Fed. R. Civ. P. 26(a)(2)(A). This disclosure, unless otherwise stipulated or ordered by the court, "must be accompanied by a written report . . . if the witness is one retained or specially employed to provide expert testimony in the case." Fed. R. Civ. P. 26(a)(2)(B). The report must contain, in pertinent part, "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i).

"The reason for requiring expert reports is 'the elimination of unfair surprise to the opposing party and the conservation of resources.' " Reed v. Binder, 165 F.R.D. 424, 429 (D.N.J. 1996) (internal quotation omitted). Nevertheless, the Third Circuit has made clear that it is unaware of any bright line rule requiring that every opinion by an expert be preliminarily stated in their expert report. See Hill v. Reederei F. Laeisz G.M.B.H., Rostock, 435 F.3d 404, 423 (3d Cir. 2006) (allowing expert's testimony, despite the fact that it exceeded the scope of his report, and noting that "the permissible scope of expert testimony is quite broad, and District Courts are vested with broad

discretion in making admissibility determinations.”). With the framework in mind, the Court turns now to Defendants’ request.

DISCUSSION

Defendants request leave to file a reply expert report addressing the issue of secondary considerations which will presumably be raised by Plaintiff in its rebuttal expert report on the issue of invalidity. Defendants explain that, because Plaintiff bears the burden of coming forward with evidence of any secondary considerations of non-obviousness, they should be given an opportunity to rebut Plaintiff’s expert’s opinions on this subject. In the alternative, Defendants request that Plaintiff be required to address secondary considerations in its opening expert report, so as to provide Defendants with an opportunity to adequately respond to same. Defendants maintain that, under the current schedule, if Plaintiff chooses to present evidence of secondary considerations in its rebuttal expert report, Defendants’ experts will have no opportunity to respond. This result would be prejudicial in light of Federal Rule of Civil Procedure 26 because – according to Defendants – they would be forced to either disclose rebuttal opinions in their opening report without the benefit of knowing the opinions they are rebutting or run the risk of preclusion from testifying.

Plaintiff, on the other hand, argues that there is no reason to modify the Court’s current scheduling order. First, Plaintiff claims that it has already provided detailed secondary consideration contentions, and has supplemented those responses as discovery has progressed. Such detailed responses are more than enough – according to Plaintiff – to put Defendants on notice of Plaintiff’s secondary consideration contentions. In any event, Plaintiff claims that Defendants’ premature request fails to meet the good cause standard given that Defendants have not yet received Plaintiff’s rebuttal expert report.

A. The “After You” Syndrome⁵

This is not the first time the undersigned has encountered this issue – namely, whether the party bearing the burden of proof on the issue of invalidity should be permitted to file a reply expert report limited to the issue of secondary considerations of non-obviousness raised by their opponent’s rebuttal expert report on invalidity. In fact, this issue has become increasingly common in Hatch-Waxman cases.⁶ As will be discussed more fully below, it is the Opinion of this Court that the recurring dispute over this issue is, in many ways, much ado about nothing – nothing except the attorneys’ perfectly understandable yet illusory perception of strategic litigation advantage.

In the words of the Honorable William G. Bassler, U.S.D.J., “[t]he Court’s analysis begins after passing through Alice’s proverbial looking-glass,⁷ into the strange, fictive realm of patent infringement” created by the Hatch-Waxman Act. Ben Venue Labs., Inc. v. Novartis Pharmaceutical Corp., 146 F. Supp. 2d 572, 577 (D.N.J. 2001). Plaintiff owns patent ‘531. Defendants each seek to sell a generic version of the drug that is an embodiment of this patent prior to its expiration. Although Defendants have not actually sold the generic, the Hatch-Waxman Act enables judicial adjudication of what the Supreme Court has described as “a highly artificial act of infringement.”

⁵ See James M. Amend, Patent Law: A Primer for Federal District Court and Magistrate Judges 6 (2006).

⁶ As the parties point out, I have, in certain cases, allowed the filing of reply expert reports. I have also denied requests to file reply expert reports. Alternatively, I have required the party bearing the burden of proof on invalidity to address secondary considerations in its opening report. I have likewise required the party bearing the burden of proof on infringement to address secondary considerations regarding invalidity in its opening report. Most of the time, the expert protocol was set at the urging or with the consent of the parties. In any event, the Court has no reason to believe that any side was prejudiced by its adherence to any one of these approaches.

⁷ See Lewis Carroll, Through the Looking-Glass, and What Alice Found There (1872).

Eli Lilly and Co. v. Medtronic, Inc., 496 U.S. 661, 678 (1990).

So begins the battle over who discloses their contentions first.⁸ Driven by what has been described as the “after you” syndrome,⁹ each side stalls – in their own tactical way – so as to better tailor their own case to the other side’s contentions. Here, Defendants want the last word on the issue of secondary considerations. In particular, Defendants claim that they should be afforded an opportunity to “rebut”¹⁰ Plaintiff’s expert’s rebuttal report on secondary considerations of non-obviousness. To do otherwise – that is, “anticipate” Plaintiff’s rebuttal before Plaintiff actually “shows its hand” – would be prejudicial, according to Defendants. However, as a practical matter, based on the following, Defendants’ rebuttal concerns are likely to be unfounded.

B. Presumption of Validity

A patent is presumed valid upon issuance. See Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1359 (Fed. Cir. 2007) (citing 35 U.S.C. § 282). Included within the presumption of validity is a presumption of non-obviousness. Id. (citation omitted). The patent challenger bears the burden of proving the factual elements of invalidity by clear and convincing evidence. See generally Shashank, supra, at § 3:2 (suggesting that this burden of proof can be satisfied “if there is an abiding conviction that the truth of its factual contentions is highly probable.”). The burden of proving invalidity remains with the challenger throughout the litigation and never shifts to the patent holder. See Pfizer, 480 F.3d at 1359 -1360.

⁸ See generally Amend, supra, at 6.

⁹ Amend, supra, at 6.

¹⁰ The Court notes that rebuttal evidence is generally defined as “evidence given in opposition to a presumption of fact or a prima facie case.” Black’s Law Dictionary 1267 (6th ed. 1990).

Nevertheless, the Federal Circuit has explained that once the challenger has presented a prima facie case of invalidity, the patent holder “has the burden of going forward with rebuttal evidence.” Id. In other words, “once a challenger introduces evidence that might lead to a conclusion of invalidity . . . the patentee ‘would be well advised to introduce evidence sufficient to rebut that of the challenger.’ ” Id. at 1360; see, e.g., Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1216 (Fed. Cir. 1998) (“While a patentee has the burden of going forward with rebuttal evidence once a challenger has presented a prima facie case of invalidity, the presumption of validity remains intact and the ultimate burden of proving invalidity remains with the challenger throughout the litigation.”). Then, “[w]ith all the evidence in, the trial court must determine whether the party on which the statute imposes the burden of persuasion has carried that burden.” Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1534 (Fed. Cir. 1983).

C. Solution

Defendants do not dispute that the party bearing the burden of proof on a particular issue should fully address the issue in its opening expert report. Nor do Defendants dispute that they bear the burden of proving invalidity by clear and convincing evidence. Included within the presumption of validity, however, is a presumption of non-obviousness.¹¹ Defendants’ burden of proving invalidity – and in this case, obviousness – remains intact throughout the litigation. This burden

¹¹ See, e.g., Structural Rubber Prods. Co. v. Park Rubber Co., 749 F.2d 707, 714 (Fed. Cir. 1984) (“[T]he party challenging validity has [the] . . . burden of overcoming the statutory presumption of validity of a patent. . . . Validity encompasses three ‘separate tests of patentability’: novelty, utility and nonobviousness. . . . Thus, included within the presumption of validity is a presumption of novelty, a presumption of nonobviousness and a presumption of utility, each of which must be presumed to have been met.”).

never shifts to Plaintiff.¹² That Plaintiff may, nevertheless, be “well-advised”¹³ in “coming forward”¹⁴ with evidence of secondary considerations of non-obviousness, has no direct bearing on Defendants’ ultimate burden of proof in this case.

That being said, the Court agrees that Defendants’ expert should be given an opportunity to adequately address secondary considerations of non-obviousness. The Court disagrees, however, that Defendants’ expert is somehow precluded from or incapable of addressing such matters in its opening report. Plaintiff’s contentions on secondary considerations of non-obviousness should come as no surprise to Defendants. First, as paragraph IV ANDA filers, Defendants have each already provided Plaintiff, the patent holder, with a detailed statement of the factual and legal basis for their respective invalidity and/or non-infringement opinions.¹⁵ Additionally, although our newly adopted Local Patent Rules¹⁶ do not speak to the issue of whether a party should be permitted to file expert reports other than the opening and rebuttal reports, Local Patent Rule 3.6 requires ultra early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-

¹² Defendants’ alternative request, namely, to require Plaintiff to address secondary considerations of non-obviousness in its opening expert report on infringement, is therefore denied.

¹³ Pfizer, 480 F.3d at 1360.

¹⁴ Mas-Hamilton Group, 156 F.3d at 1216.

¹⁵ See, e.g., Peter S. Menell et al., Patent Case Management Judicial Guide 10-5 (2009) (noting that “[t]he parties to a patent lawsuit brought under the Hatch-Waxman Act therefore usually have more information at the start of the litigation than what is available at the start of a typical patent suit.”).

¹⁶ Our Local Civil Rules were amended to include Local Patent Rules effective January 1, 2009. The new rules can be found at <http://www.njd.uscourts.gov/rules/BarOrd9.3.pdf>.

Waxman Act. See L. Pat. R. 3.6.¹⁷ Lastly, even though Local Patent Rule 3.6 went into effect on January 1, 2009 by which time discovery in this matter was well underway, this Court almost always schedules expert reports after the close of fact discovery, including contention discovery. Therefore, by the time the parties are scheduled to exchange expert reports, they should be acutely aware of the other side's contentions and/or counter contentions. Presumably, they have been fully explored and scrutinized. As a result, although secondary considerations may be characterized as rebuttal evidence,¹⁸ as a practical matter, there is no compelling reason why Defendants should not address same in their opening report.

Although the Court appreciates Defendants' concerns, here, Plaintiff has made sufficiently detailed disclosures on its secondary consideration contentions. Although a situation could arise where Plaintiff's expert raises an issue in its rebuttal report which was not adequately disclosed beforehand, there is no reason why Defendants' expert should not – as a general matter (and absent a contrary agreement by the parties) – address secondary considerations of non-obviousness in its opening report.¹⁹ Given that the parties have not yet exchanged their opening expert reports – much less their rebuttal reports – Defendants' request to submit a reply expert report is denied without

¹⁷ In particular, Local Patent Rule 3.6(b)-(e) requires the defendant in an ANDA case to provide both invalidity and non-infringement contentions within fourteen (14) days of the initial scheduling conference. Subsection (f) requires the plaintiff to provide its infringement contentions within forty-five (45) days of the defendant's disclosure of non-infringement contentions. See L. Pat. R. 3.6. This unusual reversal of the typical order and timing for disclosure allows for faster resolution of issues than in a typical patent case. See, e.g., Menell et al., supra, at 10-5.

¹⁸ See, e.g., ABB Air Preheater, Inc. v. Regenerative Envtl. Equip. Co., Inc., 167 F.R.D. 668, 672 (D.N.J. 1996) (explaining that "[e]vidence of secondary considerations is in the nature of rebuttal evidence.").

¹⁹ See, e.g., Amend, supra, at 87.

prejudice as premature. Defendants are hereby directed to address all issues related to those on which they bear the burden of proof in their opening report, namely invalidity and obviousness.²⁰ To the extent the need arises, Defendants may file an application for leave of Court to file a reply expert report which should include a detailed explanation as to why the issue, evidence or basis was not, or could not be, included in their opening report. See, e.g., Amend, supra, at 40 (suggesting that such leave should only be given upon a demonstration of resulting prejudice). The Court reiterates that it understands Defendants' concern and will therefore maintain a flexible approach to this issue to ensure that no party gains an unfair advantage or is prejudiced.

CONCLUSION

Based on the reasons set forth above, Defendants' request for leave to submit a reply expert report limited to the issue of secondary considerations of non-obviousness raised by Plaintiff in its rebuttal expert report on invalidity is **denied without prejudice**. To the extent the need arises, Defendants may renew their request once Plaintiff has filed its rebuttal report on invalidity.

DATE: February 20, 2009

Orig.: Clerk of the Court
cc: Hon. William J. Martini, U.S.D.J.
All Parties
File

/s/ Mark Falk

MARK FALK
United States Magistrate Judge

²⁰ See generally Structural Rubber Prods., 749 F.2d at 714 (noting that "included within the presumption of validity is a presumption of novelty, a presumption of nonobviousness and a presumption of utility, each of which must be presumed to have been met.").